Mallinckrodt COVIDIEN

February 7, 2013

Testimony - An Act Prohibiting Generic Substitutions for Tamper-Resistant Drug Formulations (HB 5484)

To Members of the Connecticut House of Representatives General Law Committee:

Mallinckrodt, the pharmaceuticals business of Covidien, is committed to efforts to ensure the safe prescribing, dispensing and use of prescription opioids. However, HB 5484 is unnecessary and burdensome to patients, it does not address the complex public health problem of abuse and it places additional financial burdens on patients, insurers and the healthcare system by limiting access to lower cost generic products.

HB5484 fails to account for the fact that the prescribers already may prohibit substitution by designating the brand name product as "medically necessary" either in writing on the script or verbally to a pharmacist [Connecticut statute (Sec. 17b-274)].

As it pertains to tamper-resistant/abuse-deterrent characteristics, the U.S. Food and Drug Administration ("FDA") is still developing standards to evaluate these characteristics. At present, the FDA prohibits any manufacturer from making either "tamper-resistant" or "abuse-deterrent" claims. In its January 2013 draft guidance entitled, *"Abuse-Deterrent Opioids: Evaluation and Labeling,"* the FDA states that none of the abuse-deterrent technologies designed to date have curtailed the most common method of opioid abuse – swallowing a number of intact pills or tablet.

As such, Mallinckrodt views the adoption of such technologies as one part of a comprehensive approach, including (but not limited to) (1) enhanced continuing education (with measureable outcomes) for prescribers, dispensers, patients and caregivers; (2) effective implementation of state prescription drug monitoring programs; and (3) permanent safe disposal programs for unused and unwanted drug products.

If HB5484 becomes law without the FDA articulating a formal regulatory process and standards for abuse deterrence, the regulatory uncertainty will result in patients and insurers being forced to use more expensive brand products without generic alternatives. For now, Mallinckrodt advocates implementing other measures, as described above, to ensure the safe prescribing, dispensing and use of prescription opioids.

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Therefore, Mallinckrodt urges you not to pass HB 5484 or similar bills that prohibit the substitution of generics before the FDA has established standards and implemented a regulatory review process to evaluate tamper-resistant/abuse-deterrent characteristics in both brand-name and generic opioid drug products.

Respectfully,

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